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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY-DOCKET NO.	CONFIRMATION NO.
09/151,409	09/10/1998	JAMES B. DALE	481112.410	7693

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/151,409

Applicant(s)

Date

Examiner

S. Devi, Ph.D.

Art Unit

1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 19, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44, and 54-58 ⁵⁸ are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44 and 54-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Applicant's Amendment

1) Acknowledgment is made of Applicant's amendment filed 11/19/01 (paper no. 26) in response to the Office Action mailed 08/15/01 (paper no. 25). With this, Applicant has amended the specification.

Status of Claims

2) Claims 13, 14, 18, 20, 22, 24-26, 28, 29, 33, 35, 39, 41, 43 and 45-48 have been canceled via the amendment filed 11/19/01.

Claims 12, 15-17, 19, 21, 23, 27, 30, 32, 36-38, 40, 42 and 44 have been amended via the amendment filed 11/19/01.

New claims 54-58 have been added via the amendment filed 11/19/01.

Claims 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44 and 54-58 are pending and are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection Irrelevant

5) The objection to claims 1 and 31 made in paragraph 19 of the Office Action mailed 08/15/01 (paper no. 15) was in error and does not pertain to the instant application. The Examiner regrets this inadvertent error.

Specification

6) It is noted that the instant specification contains trademark recitations, such as, "Superdex 75" (see page 16, line 28), which are not capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the

~~marks should be respected and every effort made to prevent their use in any manner which might~~
adversely affect their validity as trademarks. It is suggested that Applicant examine the whole specification to make similar corrections to the trademarks, wherever trademarks appear.

It is noted that the 'Brief Description of the Drawings' for "Figure 7" does not refer to the two panels as shown in the Drawings, i.e., Figure 7A and 7B.

Rejection(s) Moot

- 7) The rejection of claims 18, 20, 22, 24, 26, 39, 41, 43, 45 and 47 made in paragraph 15 of the Office Action mailed 08/15/01 (paper no. 15) under 35 U.S.C. 112, first paragraph, as containing new matter, is moot in light of Applicant's cancellation of the claims.
- 8) The rejection of claims 13 and 28 made in paragraph 16 of the Office Action mailed 08/15/01 (paper no. 15) under 35 U.S.C. 112, first paragraph, as containing new mater, is moot in light of Applicant's cancellation of the claims.
- 9) The rejection of claims 13, 14, 25, 28, 29 and 46 made in paragraph 17 of the Office Action mailed 08/15/01 (paper no. 15) under 35 U.S.C. § 102(b) as being anticipated by Dale *et al.* (WO 94/06421 - Applicant's IDS) ('421), is moot in light of Applicant's cancellation of the claims.
- 10) The rejection of claims 33 and 35 made in paragraph 18 of the Office Action mailed 08/15/01 (paper no. 15) under 35 U.S.C. § 103(a) as being unpatentable over Dale *et al.* (WO 94/06421 - Applicant's IDS) ('421) in combination with Pillai *et al.* (US 5,334,379), is moot in light of Applicant's cancellation of the claims.

Rejection(s) Withdrawn

- 11) The rejection of claims 16 and 37 made in paragraph 15 of the Office Action mailed 08/15/01 (paper no. 15) under 35 U.S.C. 112, first paragraph, as containing new matter, is withdrawn in light of Applicant's amendments to the claims.
- 12) The rejection of claims 12, 15, 17, 19, 21, 23, 27, 30, 31, 36, 38, 40, 42 and 44 made in paragraph 17 of the Office Action mailed 08/15/01 (paper no. 15) under 35 U.S.C. § 102(b) as being anticipated by Dale *et al.* (WO 94/06421 - Applicant's IDS) ('421), is withdrawn in light of Applicant's amendments to the claims and/or the base claim(s).

~~13)~~ The rejection of claims 27, 32 and 34 made in paragraph 18 of the Office Action mailed 08/15/01 (paper no. 15) under 35 U.S.C. § 103(a) as being unpatentable over Dale *et al.* (WO 94/06421 - Applicant's IDS) ('421) in combination with Pillai *et al.* (US 5,334,379), is withdrawn in light of Applicant's amendments to the claims and/or the base claim(s).

Applicant's Arguments Relevant to the Instant Rejection(s)

14) Those arguments of Applicant's that are relevant to the rejection(s) made in this Office Action are addressed herebelow.

With regard to the recitation of the C-terminal "peptide" being a reiteration of at least one of the immunogenic peptides, Applicant submits that the terms "immunogenic peptide" and "immunogenic polypeptide" are used interchangeably in the instant specification. See page 12 of Applicant's amendment filed 11/19/01. Applicant points to page 5, lines 25 and 26; page 6, lines 4-7 and page 20, line 28 to page 21, line 2 of the specification and states that these parts of the specification teach how to identify M protein "peptides" suitable for use as an "immunogenic polypeptide". A review of the instant specification indicates that the written description provided in the specification does not equate a "peptide" with a "polypeptide". The two terms are not defined as being synonymous or equivalent in the instant specification as originally filed. The terms are given the broadest interpretation, since the instant specification lacks a precise definition. Although an Applicant can be his/her own lexicographer, in the absence of a clear definition in the specification for a term(s), Applicant cannot interpret such a term in a way that is contrary to the definition provided by those skilled in the art. For instance, the *Concise Encyclopedia: Biochemistry and Molecular Biology* [Third Edition, (Ed) Scott TA *et al.*, Walter de Gruyter, New York, 1997, p. 489] defines the term "peptides" as organic compounds consisting of *two* or more amino acids joined covalently by peptide bonds (see attachment). "Polypeptides" are defined as those that contain *more than 10* residues. The scope of the limitation "peptide" used in the specification and in the claims, for example, in part (b) and part (ii) of claims 12 and 27 respectively, does not appear to be the same. As recited currently, the C-terminal peptide which is a reiteration of "at least one immunogenic peptide" from the amino-terminal of "the" immunogenic portion is structurally not the same as one of the "immunogenic peptides" recited in part (a) of claim 12 or part (ii) of claim 27. The "at least one immunogenic

peptide” of part (b) of claim 12 and part (ii) of claim 27 can be a less than ten amino acid-long peptide.

New Rejection(s)

Applicant is asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicant’s amendments to the claims and/or the base claim.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

15) Claims 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44 and 49-58 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a recombinant fusion polypeptide or a composition comprising the same, wherein the fusion polypeptide comprises a multivalent immunogenic portion comprising at least two immunogenic peptides, each at least ten amino acids long and with the capacity to elicit an immune response against Group A *Streptococci* and a C-terminal peptide that “is a reiteration of at least one immunogenic peptide from the amino-terminal of the immunogenic portion” and is not required to stimulate an immune response against Group A *Streptococci*. Applicant points to Examples 1 and 4 and Figure 7 and state that these parts provide support for the amendments introduced to the base claims 12 and 27. However, neither the brief description for Figure 7, nor Figure 7 itself, provide descriptive support for the newly added limitations introduced to part (b) of claims 12 and 27. Similarly, Examples 1 and 4 do not appear to provide descriptive support for the added limitations: wherein the C-terminal peptide “is a reiteration of at least one immunogenic peptide from the amino-terminal of the immunogenic portion”. On page 2 of the specification it is recited that the C-terminal peptide may be an inconsequential “non-immunogenic peptide” or a reiterated “immunogenic polypeptide”.

The recitation “immunogenic peptides” comprised in the immunogenic portion in part (a) of base claim 12 and part (ii) of claim 27 is not supported in the specification. Instead, part (a) of the claimed fusion polypeptide is consistently described as containing “immunogenic polypeptides”. There appears to be no support for the new limitation “multivalent immunogenic portion” as recited. Claims 16 and 37, as amended, include the limitations: “consists of six

immunogenic peptides, wherein the peptides are an amino-terminal of at least one M protein”.

However, there appears to be no descriptive support for such limitations. Examples 1 and 4 and Figure 7 do not appear to provide support for the newly added limitations. Therefore, the limitations in the claims identified above are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to remove the new matter from the claims, or point to specific parts of the disclosure that provide descriptive support for the limitation identified above.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

16) Claims 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44 and 49-58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 12 and 27 are confusing in the recitation “wherein the C-terminal peptide is a reiteration of at least one immunogenic peptide from the amino-terminal of the immunogenic portion and is not required to stimulate an immune response against Group A Streptococci”. In part (a) of claim 12 or part (i) of claim 27, the “immunogenic peptides” are recited as being “capable of eliciting an immune response against Group A Streptococci”. A peptide described as an “immunogenic peptide” would necessarily be immunogenic. Yet in part (b) of claim 12 or (ii) of claim 27, a reiteration of “at least one” immunogenic peptide (from the amino terminal of the immunogenic portion) is recited as not being required to stimulate an immune response against Group A Streptococci. Note that the recitations “at least one immunogenic peptide” in part (b) of claim 12 and part (ii) of claim 27 lack antecedent basis and therefore need not be one of “the” same immunogenic peptides from part (a) of claim 12 or part (ii) of claim 27. The scope of the structural and/or functional composition of the “immunogenic peptide(s)” recited in parts (a) and (b) of claim 12 and parts (i) and (ii) of claim 27 is indeterminate.

(b) Claims 15-17, 19, 21, 23, 30-32, 34, 36-38, 40, 42, 44 and 49-58, which depend directly or indirectly, from claims 12 or 27 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, because of the vagueness or indefiniteness identified above in the

base claims.

Remarks

17) Claims 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44 and 54-58 stand rejected.

18) The Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9306.

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

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Any inquiry of a general nature or relating to the status of this application or proceeding
should be directed to the Group receptionist whose telephone number is (703) 308-0196.


S. DEVI, PH.D.
PRIMARY EXAMINER

March 2002